Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—To an accurately measured volume of Injection, equivalent to about 500 mg of calcium gluconate, add 2 mL of 3 N hydrochloric acid, and dilute with water to 150 mL. While stirring, preferably with a magnetic stirrer, add about 20 mL of 0.05 M edetate disodium VS from a 50-mL buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 2.004 mg of calcium (Ca).

Calcium Gluconate Tablets

DEFINITION

Calcium Gluconate Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of calcium gluconate ($C_{12}H_{22}CaO_{14}$).

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL,** *Calcium* ⟨**191**⟩
  Sample stock solution: A warm, filtered solution in water, equivalent to 100 mg/mL of calcium gluconate from powdered Tablets
  Sample solution: Equivalent to 20 mg/mL of calcium gluconate from a dilution of the *Sample stock solution*
  Acceptance criteria: Meet the requirements
- **B. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST**
  Standard solution: 10 mg/mL of USP Potassium Gluconate RS
  Sample solution: Equivalent to 10 mg/mL of calcium gluconate from a dilution of the *Sample stock solution* obtained from *Identification* test *A*
  Chromatographic system
  (See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.)
  Adsorbent: 0.25-mm layer of chromatographic silica gel
  Application volume: 5 µL
  Developing solvent system: Alcohol, ethyl acetate, ammonium hydroxide, and water (50:10:10:30)
  Spray reagent: Dissolve 2.5 g of ammonium molybdate in 50 mL of 2 N sulfuric acid in a 100-mL volumetric flask, add 1.0 g of ceric sulfate, swirl to dissolve, and dilute with 2 N sulfuric acid to volume.
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Develop until the solvent front has moved about three-fourths of the length of the plate. Remove the plate, and dry at 110° for 20 min. Allow to cool, and spray with *Spray reagent.* Heat the plate at 110 ° for about 10 min.
  Acceptance criteria: The principal spot of the *Sample solution* corresponds in color, size, and R_F value to that of the *Standard solution.*

ASSAY

- **PROCEDURE**
  Sample: A portion of the powder from NL T 20 finely powdered Tablets, equivalent to 500 mg of calcium gluconate
  Blank: Proceed as directed in the *Analysis*, without the *Sample.*
  Titrimetric system
  (See *Titrimetry* ⟨541⟩.)
  Mode: Direct titration
  Titrant: 0.05 M edetate disodium VS
  Indicator: Hydroxy naphthol blue, 300 mg
  Endpoint detection: Visual
  Analysis: Transfer the *Sample* to a suitable crucible. Ignite, gently at first, until free from carbon. Cool the crucible. Add 10 mL of water, and dissolve the residue by adding sufficient 3 N hydrochloric acid, dropwise, to achieve complete solution. Transfer the solution to a suitable container, and add about 150 mL of water. While stirring, preferably with a magnetic stirrer, add 20 mL of *Titrant* from a 50-mL buret. Add 15 mL of 1 N sodium hydroxide, then add the *Indicator*. Continue the titration to a blue endpoint. Per form a *Blank* determination.
  Calculate the percentage of the labeled amount of calcium gluconate ($C_{12}H_{22}CaO_{14}$) in the portion of T ablets taken:

$$\text{Result} = \{[(V_S - V_B) \times M \times F]/W\} \times 100$$

  V_S = *Titrant* volume consumed by the *Sample* (mL)
  V_B = *Titrant* volume consumed by the *Blank* (mL)
  M = actual molarity of the *Titrant* (mM/mL)
  F = equivalency factor, 430.4 (mg/mM)
  W = nominal weight of calcium gluconate in the *Sample* (mg)
  Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

- **DISSOLUTION** ⟨**711**⟩
  Medium: Water; 900 mL
  Apparatus 2: 50 rpm
  Time: 45 min
  Standard solution: Solution having a known concentration of calcium in *Medium*
  Sample solution: Filtered portion of the solution under test, suitably diluted with *Medium* if necessary
  Instrumental conditions
  (See *Spectrophotometry and Light-Scattering* ⟨851⟩.)
  Mode: Atomic absorption spectrophotometry
  Analytical wavelength: 422.8 nm
  Lamp: Calcium hollow-cathode
  Flame: Air–acetylene
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Calculate the percentage of the labeled amount of calcium gluconate ($C_{12}H_{22}CaO_{14}$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S \times D \times V/L) \times (M_r/A_r) \times 100$$

  A_U = absorbance of the *Sample solution*
  A_S = absorbance of the *Standard solution*
  C_S = concentration of calcium in the *Standard solution* (mg/mL)
  D = dilution factor for the *Sample solution*
  V = volume of *Medium*, 900 mL
  L = label claim (mg/Tablet)
  M_r = molecular weight of calcium gluconate, 430.4
  A_r = atomic weight of calcium, 40.078
  Tolerances: NLT 75% (Q) of the labeled amount of calcium gluconate ($C_{12}H_{22}CaO_{14}$) is dissolved.
- **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Potassium Gluconate RS

Calcium Hydroxide

$Ca(OH)_2$ 74.09
Calcium hydroxide.
Calcium hydroxide [1305-62-0].

» Calcium Hydroxide contains not less than 95.0 percent and not more than 100.5 per cent of $Ca(OH)_2$.

Packaging and storage—Preserve in tight containers.

Identification—

A: When mixed with from three to four times its weight of water, it forms a smooth magma. The clear, supernatant from the magma is alkaline to litmus.

B: Mix 1 g with 20 mL of water, and add sufficient 6 N acetic acid to effect solution: the resulting solution responds to the tests for *Calcium* ⟨191⟩.

Limit of acid-insoluble substances—Dissolve 2.0 g in 30 mL of 4 N hydrochloric acid, and heat to boiling. Filter the mixture, wash the residue with hot water, and ignite: the weight of the residue does not exceed 10 mg (0.5%).

Carbonate—Mix 2 g with 50 mL of water: the addition of an excess of 3 N hydrochloric acid to the mixture does not cause more than a slight effer vescence.

Heavy metals ⟨231⟩**—**Dissolve 2.0 g in 20 mL of 3 N hydrochloric acid, and evaporate on a steam bath to dr yness. Dissolve the residue in 20 mL of water, and filter. Dilute the filtrate with water to 40 mL, and to 20 mL of the resulting solution add 1 mL of 0.1 N hydrochloric acid, then add water to make 25 mL: the limit is 20 µg per g.

Limit of magnesium and alkali salts—Dissolve 0.50 g in a mixture of 30 mL of water and 10 mL of 3 N hydrochloric acid, and proceed as directed in the test for *Magnesium and alkali salts* under *Calcium Carbonate*, beginning with "heat the solution, and boil for 1 minute." The weight of the residue does not exceed 12 mg (4.8%).

Assay—Transfer about 1.5 g of Calcium Hydroxide, accurately weighed, to a beaker, and gradually add 30 mL of 3 N hydrochloric acid. When the solution is dissolved, transfer it to a 500-mL volumetric flask, rinse the beaker thoroughly, adding the rinsings to the flask, dilute with water to volume, and mix. Pipet 50 mL of the solution into a suitable container, add 100 mL of water, 15 mL of 1 N sodium hydroxide, and 300 mg of hydroxy naphthol blue, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 3.705 mg of $Ca(OH)_2$.

Calcium Hydroxide Topical Solution

» Calcium Hydroxide Topical Solution is a solution containing, in each 100 mL, not less than 140 mg of calcium hydroxide [$Ca(OH)_2$].

Prepare Calcium Hydroxide Topical Solution as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩):

Calcium Hydroxide	3 g
Purified Water	1000 mL

Add the Calcium Hydroxide to 1000 mL of cool Purified Water, and agitate the mixture vigorously and repeatedly during 1 hour. Allow the excess calcium hydroxide to settle. Dispense only the clear supernatant.

NOTE—The solubility of calcium hydroxide, which varies with the temperature at which the solution is stored, is about 170 mg per 100 mL at 15 ° and less at a higher temperature. The official concentration is based upon a temperature of 25°.

The undissolved portion of the mixture is not suitable for preparing additional quantities of Calcium Hydroxide Topical Solution.

Packaging and storage—Preserve in well-filled, tight containers, at a temperature not exceeding 25 °.

Identification—

A: It absorbs carbon dioxide from the air, a film of calcium carbonate forming on the sur face of the liquid.

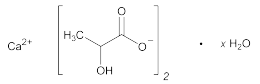
B: When heated, it becomes turbid, owing to the separation of calcium hydroxide.

C: It responds to the tests for *Calcium* ⟨191⟩.

Alkalies and their carbonates—A portion of it, saturated with carbon dioxide and subsequently boiled, is neutral in reaction.

Assay—Pipet 100 mL of T opical Solution into a suitable container, add 50 mL of water, 15 mL of 1 N sodium hydroxide, and 300 mg of hydroxy naphthol blue, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 3.705 mg of calcium hydroxide [$Ca(OH)_2$].

Calcium Lactate



$C_6H_{10}CaO_6 \cdot 5H_2O$ 308.30

$C_6H_{10}CaO_6$ 218.22

Propanoic acid, 2-hydroxy-, calcium salt (2:1), hydrate;
Calcium lactate (1:2) hydrate [41372-22-9].
Calcium lactate (1:2) pentahydrate [5743-47-5].
Anhydrous [814-80-2].

DEFINITION

Calcium Lactate contains NLT 98.0% and NMT 101.0% of calcium lactate ($C_6H_{10}CaO_6$), calculated on the dried basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL,** *Calcium* ⟨**191**⟩**:** Meets the requirements
- **B. INFRARED ABSORPTION** ⟨**197K**⟩

ASSAY

- **PROCEDURE**

Sample: Weighed portion of Calcium Lactate equivalent to 350 mg of $C_6H_{10}CaO_6$

Blank: 150 mL of water and 2 mL of 3 N hydrochloric acid

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in a mixture of water and 3 N hydrochloric acid (150:2). While stirring with a magnetic stirrer, add 30 mL of *Titrant* from the titration buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Perform the *Blank* determination.

Calculate the percentage of calcium lactate ($C_6H_{10}CaO_6$) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times M \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)
V_B = *Titrant* volume consumed by the *Blank* (mL)
M = *Titrant* molarity (mM/mL)
F = equivalency factor, 218.2 mg/mM
W = *Sample* weight (mg)

Acceptance criteria: 98.0%–101.0% on the dried basis

IMPURITIES

- **HEAVY METALS** ⟨**231**⟩

Test preparation: Dissolve 1 g in 2.5 mL of 1 N acetic acid, and dilute with water to 25 mL.